A Study on Causes and Management of Enterocutaneous Fistula

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Abstract: *Enterocutaneous fistulas still have a high unacceptable mortality rate and their management is very complex and is a big challenge to the surgeon. It results in some serious complications that lead to prolonged hospitalization and high cost of treatment. It also causes severe psychological distress to the patient due to severe pain and discomfort. Enteric fistulas, occurring spontaneously or in the postsurgical period, represent a significant management challenge and may result in both morbidity and occasionally mortality for the patient. The care in these patients may be complex and has led to the establishment of specialized intestinal failure units, aimed at optimizing outcome.This study is restricted only to postoperative fistulas. Properly staged definitive procedure after correcting the sepsis and improving the nutrition of the patient leads to the best results.*

I. Introduction

Enterocutanous fistula may be primary or secondary. Primary fistulas occur as a consequence of underlying disease in the bowel like Crohn's disease or malignancy. Other factors are post radiation therapy for malignancy, distal obstruction; iatrogenic or spontaneous bowel injury, complicated intra-abdominal infections such as tuberculosis, amoebiasis, and typhoid, or diverticular disease (3). Secondary fistulas occur as a consequence of injury to an otherwise normal gut during surgical or endoscopic procedures. The majority of the fistulas (75% to 85%) are of the secondary type following surgeries (4). It commonly occurs due to anastomotic leaks, intraoperative injury to the bowel or its blood supply, erosion from intra-abdominal tubes or drains, placements of prosthetic meshes and misplacement of sutures while closing the abdominal wall. Fistulas may also develop after percutaneous drainage of abscess or a hematoma. Enterocutaneous fistulas still have a high unacceptable mortality rate and their management is very complex and is a big challenge to the surgeon. It results in some serious complications that lead to prolonged hospitalization and high cost of treatment. It also causes severe psychological distress to the patient due to severe pain and discomfort. Also, malodorous discharge from the fistula creates a stigma to the patients and their relatives. The most common reasons for high mortality are sepsis followed by malnutrition.

II. Material And Methods

21 Successful patients who develop enterocutaneous fistulas following elective or emergency surgeries done in this institute during the study period and 2 patients who were referred to this institute with postsurgical enterocutaneous fistula are studied prospectively. Patients were managed in four stages according to Shackelford's guidelines (6). The patients were selected based on the following inclusion and exclusion criteria.

Study Location: This was a tertiary care teaching hospital based study done in Department of General surgery , Coimbatore medical college Hospital, Coimbatore, Tamilnadu.
Study Duration: July 2017 to July 2018
***I*nclusion criteria:**
1) patients developing enterocutaneous fistulae in Postoperative period.
2) patients referred with postsurgical enterocutaneous fistula for further

Exclusion criteria:
1) patients with oesophageal, biliary, pancreatic and anal fistulae.
2) patients with primary enterocutaneous fistulae due to causes other than postsurgical.
3) pregnant patients.
4) psychiatry patients.
5) patients below 15 years of age

Patients were initially stabilised with aggressive correction of fluid and electrolyte imbalances in the first 48 to 72 hours. Fluid input was given in accordance to their renal parameters and the fistulous output. Strict input and output charts were maintained and urine output was maintained at a minimum of 0.5 ml/kg/hr. Inotropes were used if the patients fail to respond to fluid resuscitation alone. Patients were monitored for signs of overhydration like pulmonary edema or pedal edema. Isotonic fluids like normal saline or Ringer's lactate solution was used to correct fluid loss. Serum electrolytes including sodium and potassium were estimated 6th hourly and corrected as and then required. Serum calcium was also estimated once daily and correction was given if necessary.

The need for transfusion was evaluated based on the hemodynamical status, haemoglobin and haematocrit of the patients of the patient. Vigorous monitoring of the patient in our surgical intensive care unit was done. They were started on intravenous third generation cephalosporins and proton pump inhibitors and anti-emetics if needed. Analgesic usage was titrated to the patient's needs. Opioid analgesics were preferred if the initial surgery was due to perforated peptic ulcer or in the presence of renal failure. The fistulous output and blood were sent for microbiological analysis. Leucocyte counts were done daily and antipyretics were used along with tepid sponging to bring down the temperature if the patients develop fever as 20 needed Higher antibiotics were used if the sepsis persists and patient wo rsens. Subsequent antibiotic therapy is modified in accordance to the patients' culture and sensitivity reports Intravenous human albumin and fresh frozen plasma were administered correct the hypoalbuminemia and patients were maintained in a positive nitrogen balance.

The fistula was classified based on the anatomy of the fistula and the output of the fistula. The fistula output was calculated either directly from drains if possible or by counting the number of pads soaked for 24 hours. The skin around the fistula is daily dressed using zinc oxide ointment to reduce excoriation and using plaster adhesives is reduced as much as possible. The choice of this method was made due to low cost as compared to costly wound collecting devices. Inj. Octreotide 100 micrograms was given thrice daily subcutaneously for 14 daysif there is reduction in the output. If there is no reduction in the output it was stopped after 5 days.

Central venous access was obtained through the patients right internal jugular vein for purpose of administering large amounts of fluids electrolytes and total parenteral nutrition. Nutrition support was started as soon as the patient is stabilized. Enteral nutrition was preferred if possible either through a jejunostomy tube if it was 21 already in place or through oral route in case of very distal fistulas. Patients were fed with a protein rich preparation and hypotonic solutions were avoided. High osmolality oral rehydration solutions were preferred when available or regular WHO's ORS was used. Whenever possible the fistula output was entirely refed into a distal feeding enterostomy tube. The daily delivered volume should include both maintenance fluids and ongoing fistulous losses. Total parenteral nutrition was given to patients as the only form of nutrition if enteral nutrition is not possible or a supplement to enteral feeding as subjected to availability in our institution using a prepacked mixture of amino acids, dextrose and lipids. Patients were given a minimum of 3000kcal/day as recommended by Raafat et al (7). Patients were monitored for development of complications from total parenteral nutrition. After stabilising the patient then imaging studies are done to define the anatomy of the fistula. Ultrasonogram and Computed Tomography was done to look for any localized intraperitoneal collections or abscesses and also to rule out distal obstruction. Once the fistula anatomy is defined then if required exteriorization of the fistula is done along with a distal mucous fistula or a tube enterostomy for feeding as temporary procedure any distal obstruction is removed using a proximal defunctioning stoma. Any abscess or collection in drained and thorough wash given. 22 Definitive procedure is done only once the patient becomes hemodynamically stable, after improving the nutrition status of the patient, resolution of sepsis and there is no sign of spontaneous closure. During this entire period various parameters were analysed and recorded for the purpose of this study. One patient had recurrence of fistula following surgical closure of the fistula and she was managed in the same way as the first time she developed the fistula.

Statistical analysis

Data was analyzed using SPSS version 20 (SPSS Inc., Chicago, IL). Student's *t*-test was used to ascertain the significance of differences between mean values of two continuous variables and confirmed by nonparametric Mann-Whitney test. In addition, paired *t*-test was used to determine the difference between baseline and 2 years after regarding biochemistry parameters, and this was confirmed by the Wilcoxon test which was a nonparametric test that compares two paired groups. Chi-square and Fisher exact tests were performed to test for differences in proportions of categorical variables between two or more groups. The level $P < 0.05$ was considered as the cutoff value or significance.

III. Result

Total number of patients included in this study is 22. Of these 14 were males and 8 were females. Ages were from 35 to 72 years with a mean of 55 years with a standard deviation of 10 years. The mean age of males was 56 while females was 54.
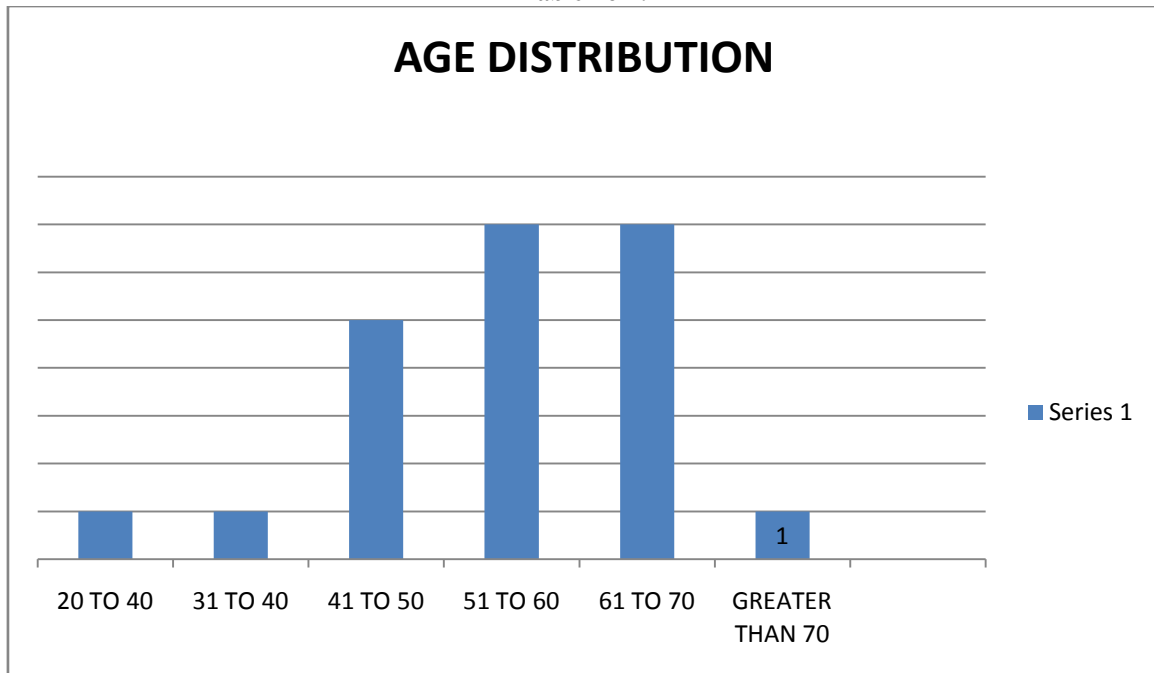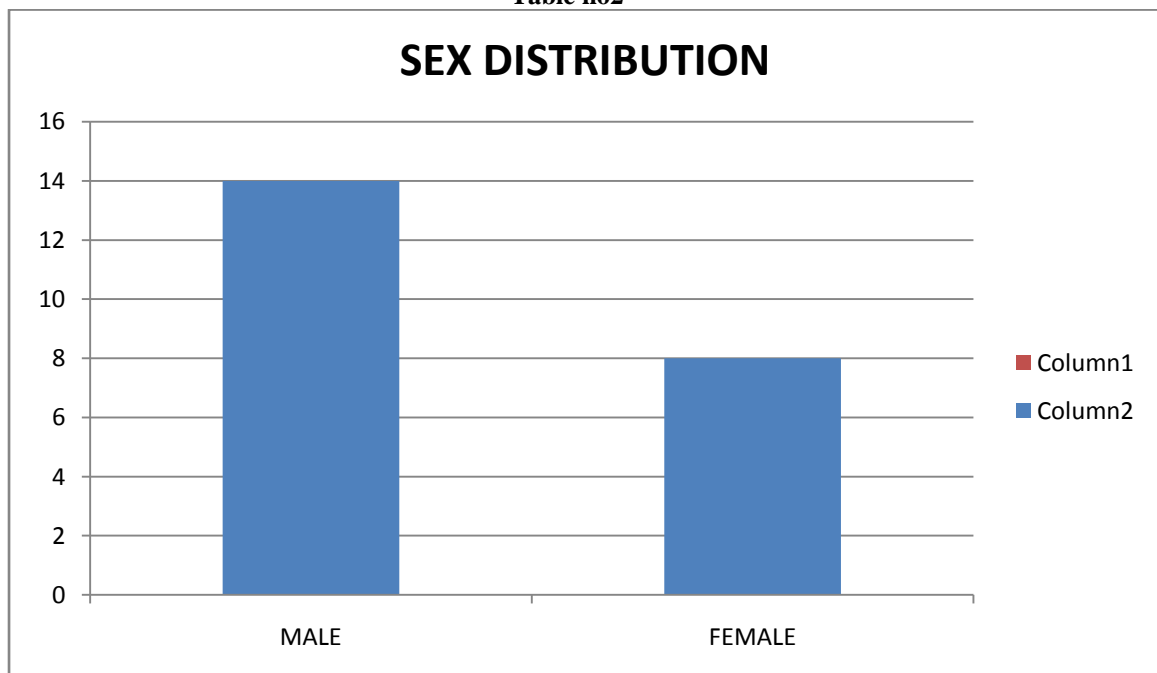
Table no 1:

Table no2

Of the 22 patients with postoperative enterocutaneous fistula, 19 were operated at this institute while 3 were referred from outside hospitals.

In 20 of these patients the initial surgery was an emergency procedure whereas in 2 patients the procedure was elective.
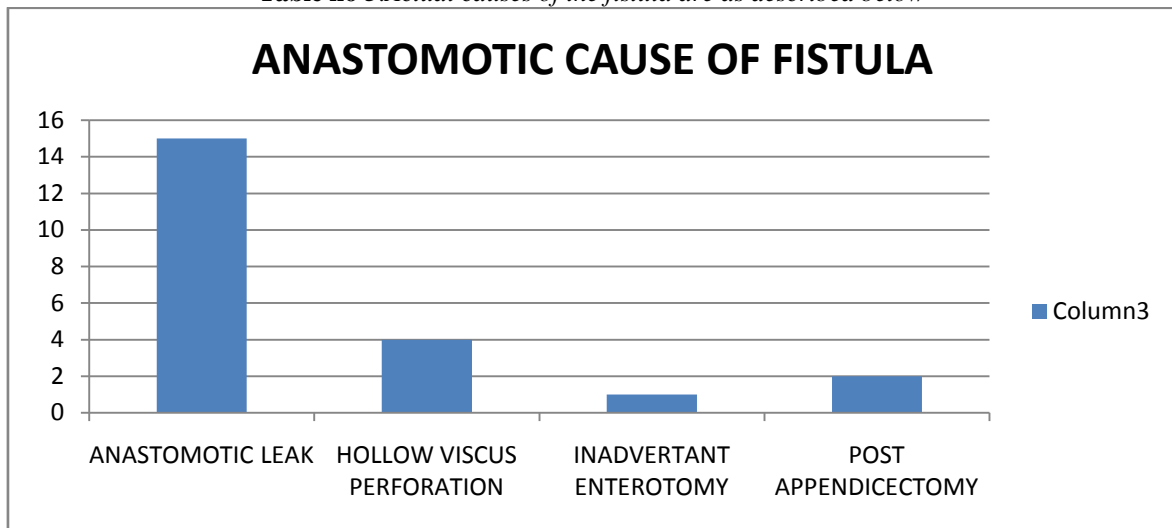
EMERGENCY VS ELECTIVE

- EMERGENCY
- ELECTIVE
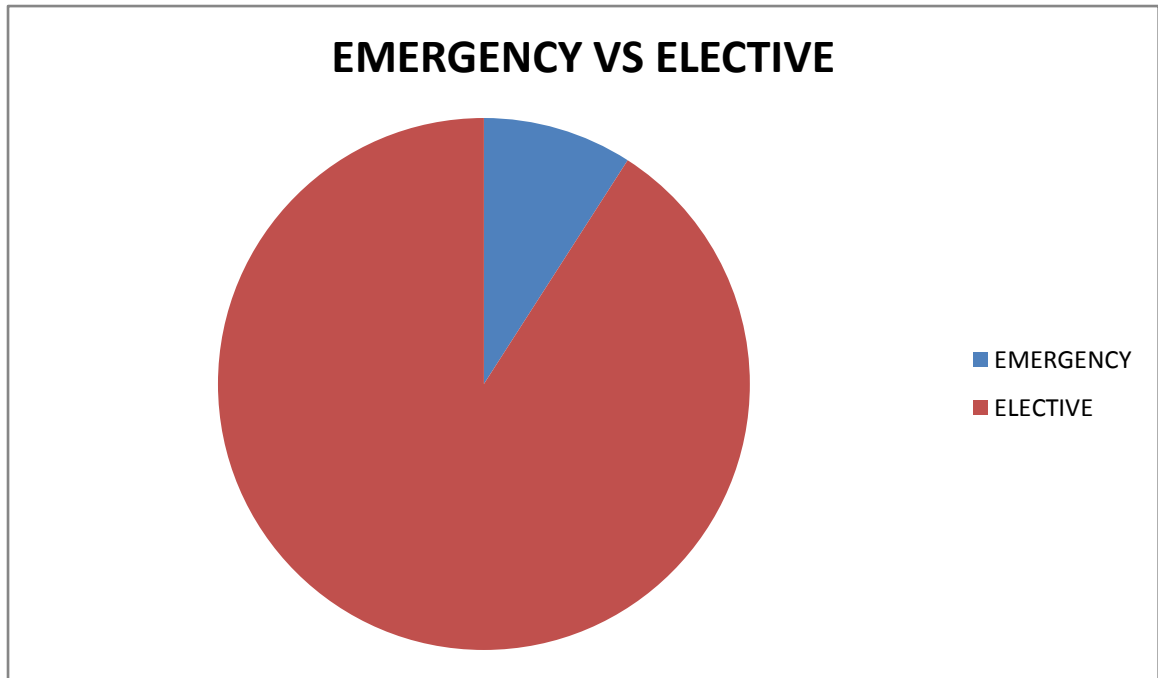
Table no 5:*Actual causes of the fistula are as described below*


ANASTOMOTIC CAUSE OF FISTULA

- Column3

Classifying on the basis of anatomical location of the fistula they were 3 gastric fistulas, 5 jejunal fistulas, 9 ileal fistulas, 2 caecal fistulas and 3 colonic fistulas. Small intestine fistulas were more common than large intestinal and gastric fistulas.

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ANATOMICAL SITES OF FISTULA

Legend:
- GASTRIC
- JEJUNUM
- ILEUM
- CAECUM
- COLON
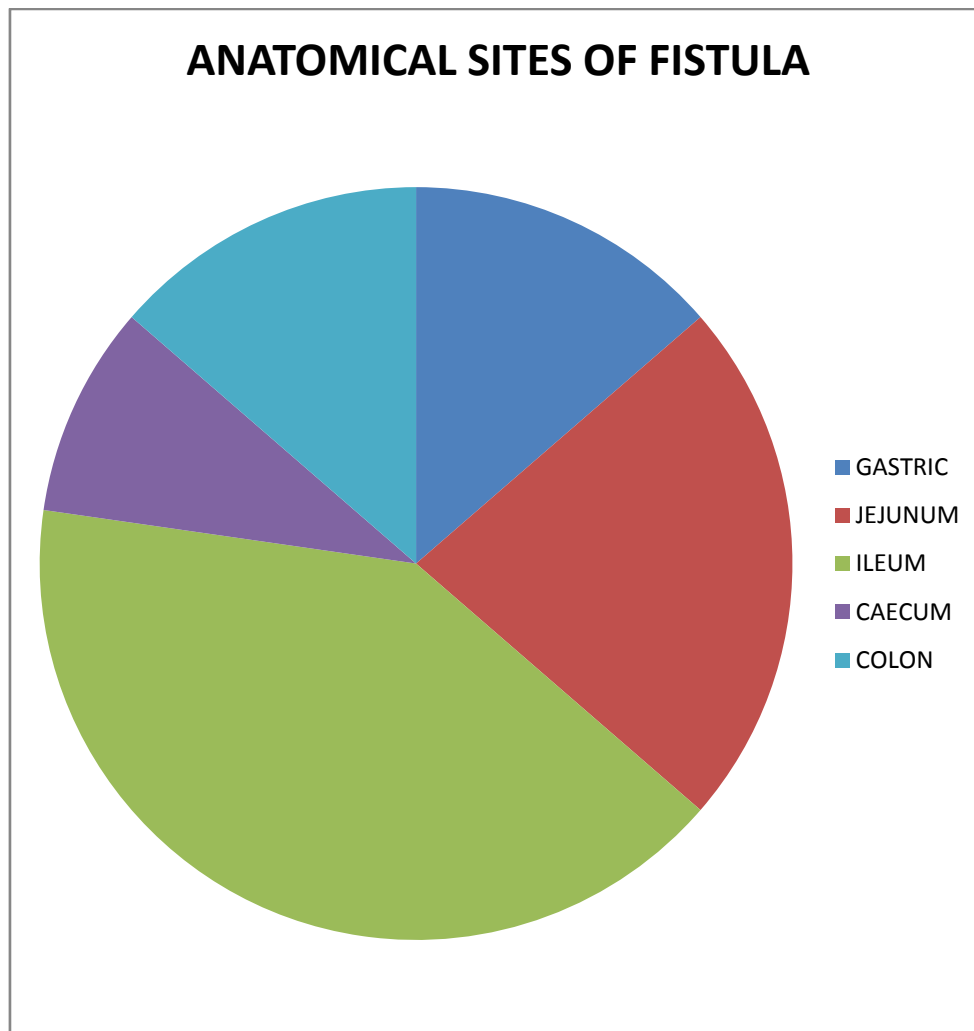
Classifying fistulas according to the quantity of output we have 5 low output fistulas (<200ml), 6 Medium output fistulas (200 to 500ml) and 11 high output fistulas (>500ml).


CLASSIFICATION BASED ON OUTPUT

Series 1
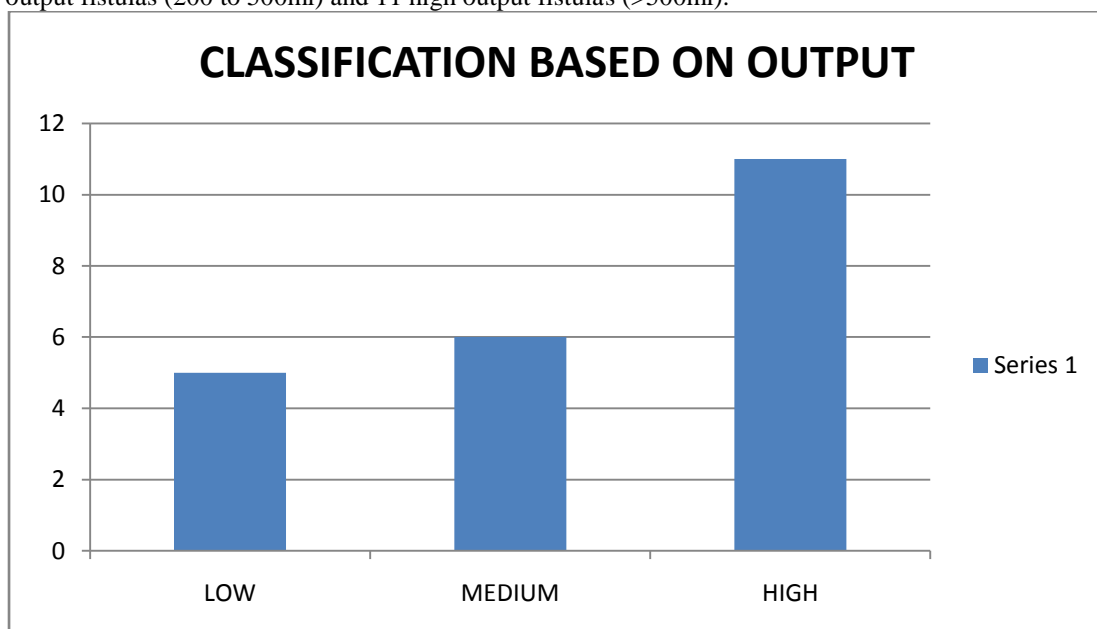
OUTPUT OF THE FISTULA BASED ON SITE
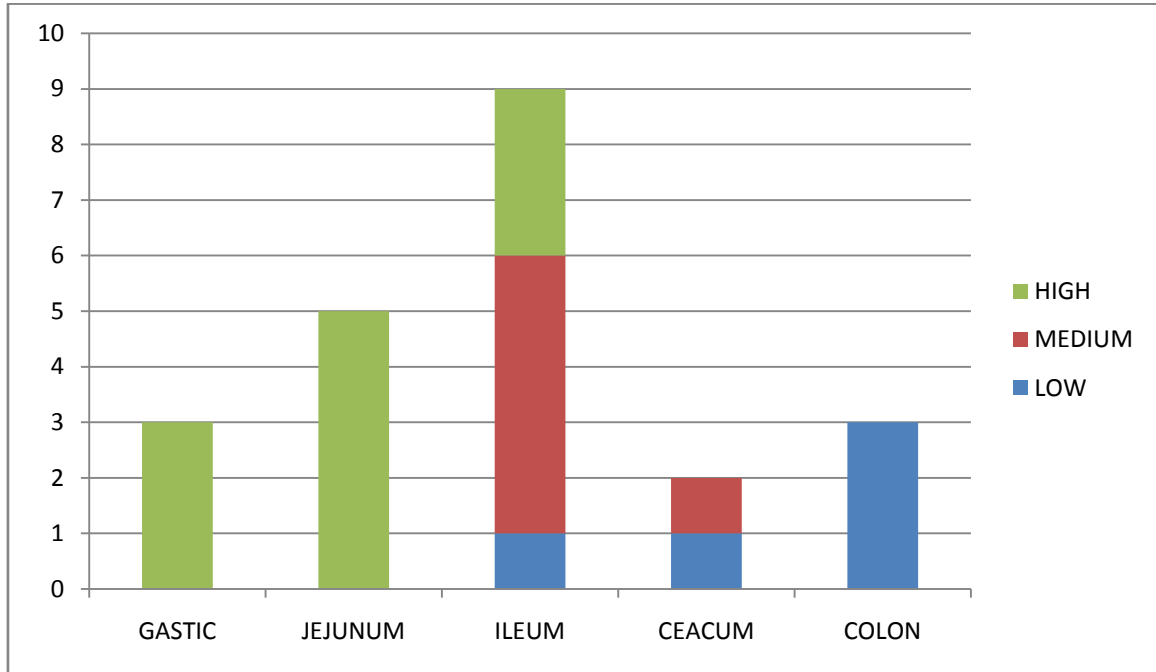
Of these gastric and jejunal fistulas were all high output fistulas and colonic fistulas were always low output fistulasIleum had 1 low output, 5 medium output and 3 high output fistulas and caecum had one low output and one medium output fistulas.

In this study 8 (36.36%) cases underwent spontaneous closure and 8 cases (36. 36%) underwent surgical closure. The remaining 6 patients (22.22%) succumbed to the disease at some point. Of the gastric fistulas, 1 (33.33%) closed spontaneously while of the 9 ileal fistulas 2 (28.57%) closed spontaneously. None of the jejunal fistulas closed spontaneously while all of the caecal and colonic fistulas closed spontaneously. The p value is 0.11.

*SPONTANEOUS CLOSURE AND SITES OF FISTULAS*
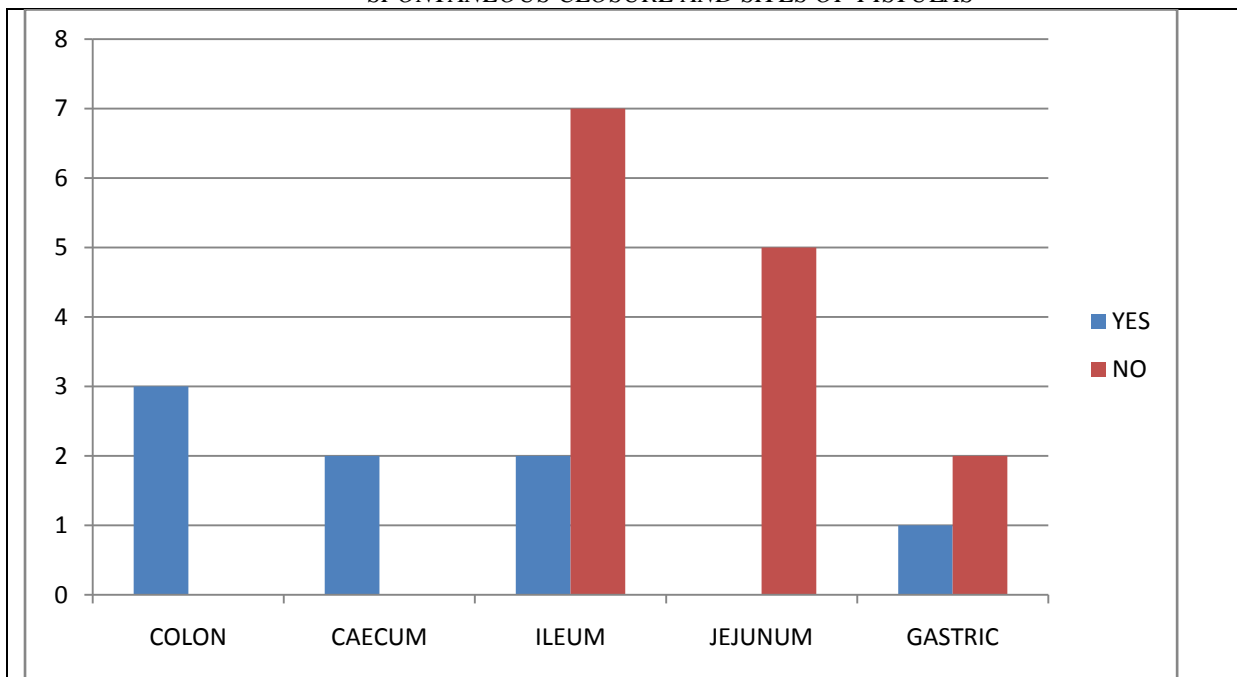
YES	3	2	2	0	1
NO	0	0	7	5	2

P VALUE - 0.116

Comparing the output of the fistulas and the spontaneous closure rates we can see that all of the 5 (100%) low output fistulas had spontaneous closure whereas 2 (33.33%) of the medium output fistulas underwent spontaneous closure and only 1 (9%) of the high output fistulas underwent spontaneous closure. The p value is statistically significant. (0.01)
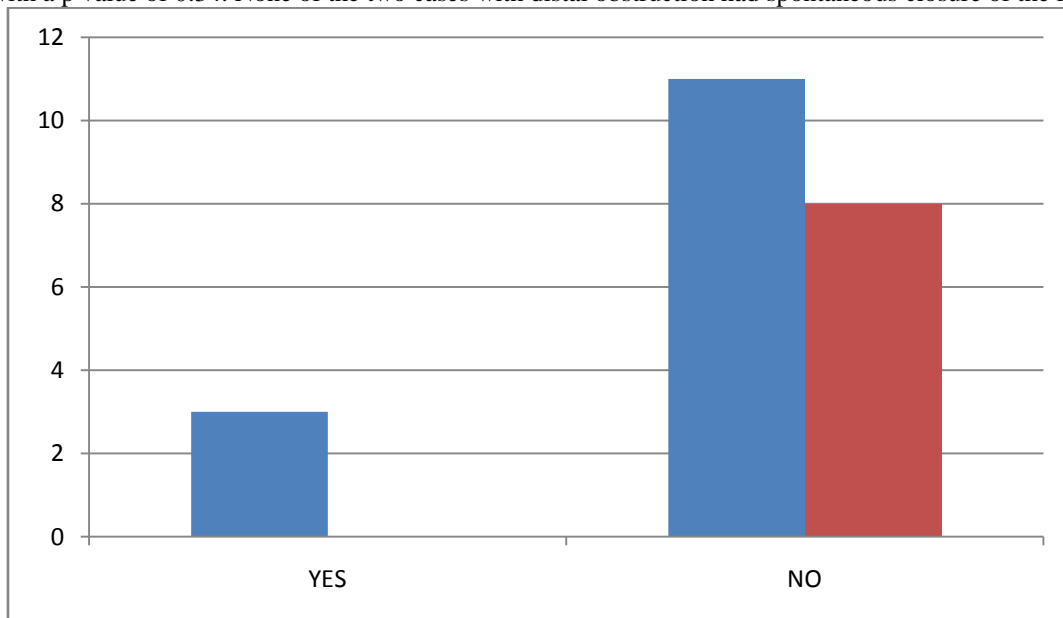
SPONTANEOUS CLOSURE AND OUTPUT OF THE FISTULAS
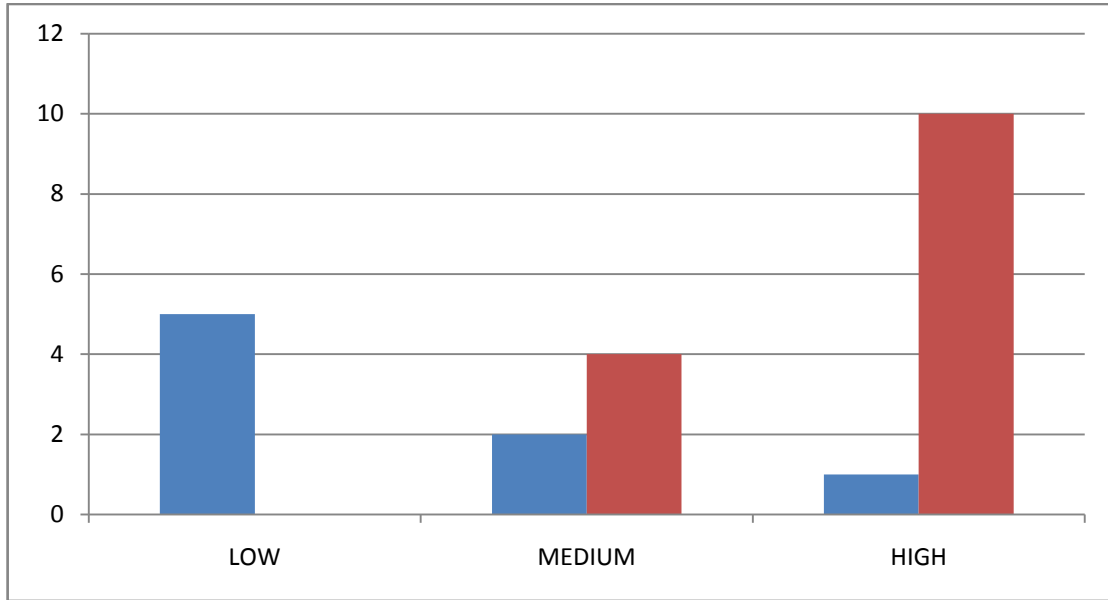
|	LOW	MEDIUM	HIGH
YES	5	2	1
NO	0	4	10

P VALUE-0.01

Comparing the presence of distal obstruction to the rates of spontaneous closure we get the following data with a p value of 0.34. None of the two cases with distal obstruction had spontaneous closure of the fistula.

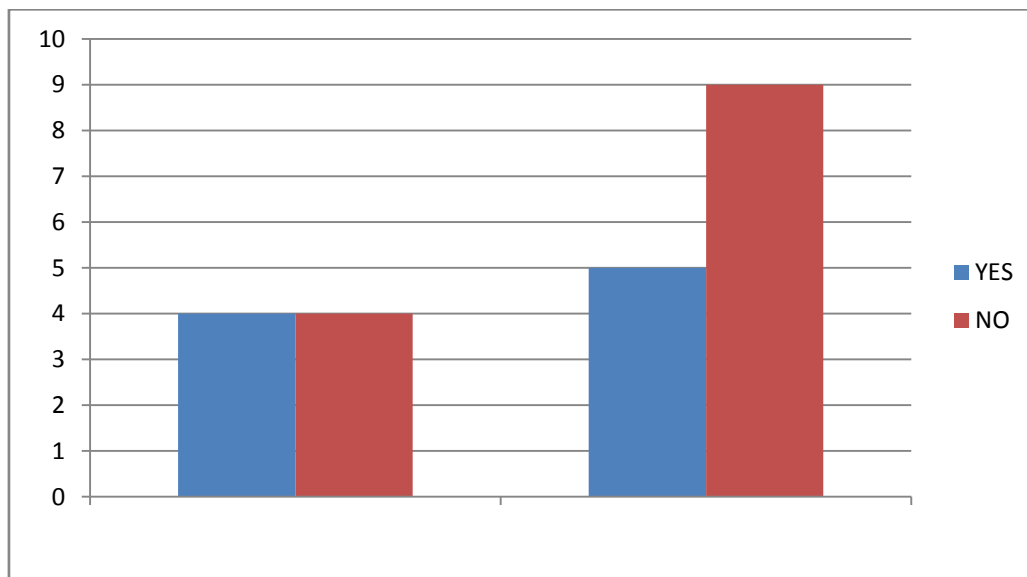|	YES	NO
NO	3	11
YES	0	8

DISTAL OBSTRUCTION
P VALUE-0.344

Comparing the rate of spontaneous closure with diabetes we get the following values with a p value or 0.60 which is not significant
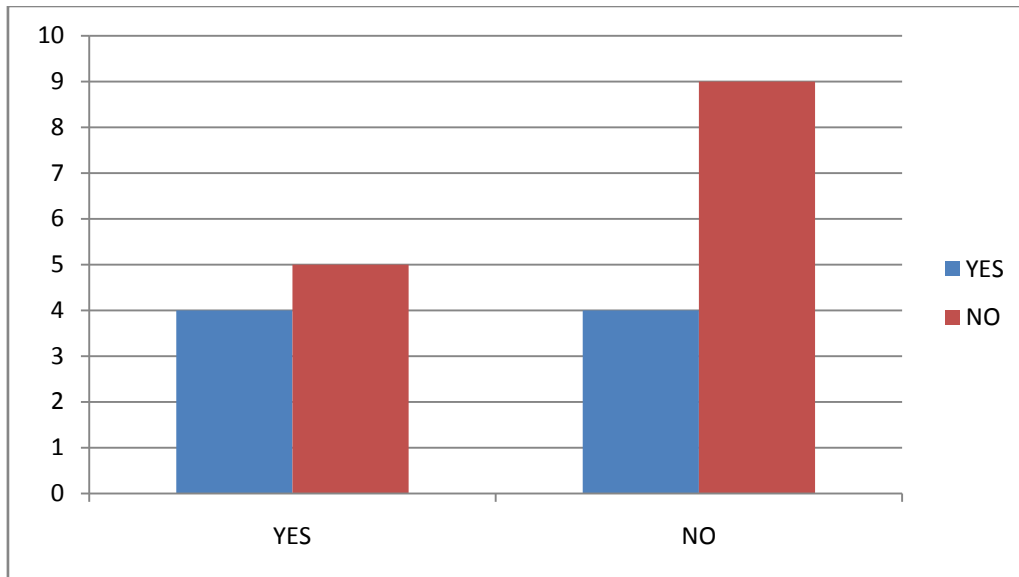
|	YES	NO
YES	4	5
N0	4	9

SPONTANEOUS CLOSURE
P VALUE-.060

Comparing the Rate of spontaneous closure with hypertension we get the following values with a p value of 0.51.

	YES	NO
YES	4	5
NO	4	9

The mean duration of number of days of closure is 21.7 days. One case had closure of the fistula in less than 10 days, 2 cases between 10 to 19 days, 3 cases between 20 to 29 days, 2 cases between 30 to 40 days and 1 case greater than 40 days.

The serum total proteins and the serum albumin levels of the patients were divided into categories and their distribution is as follows
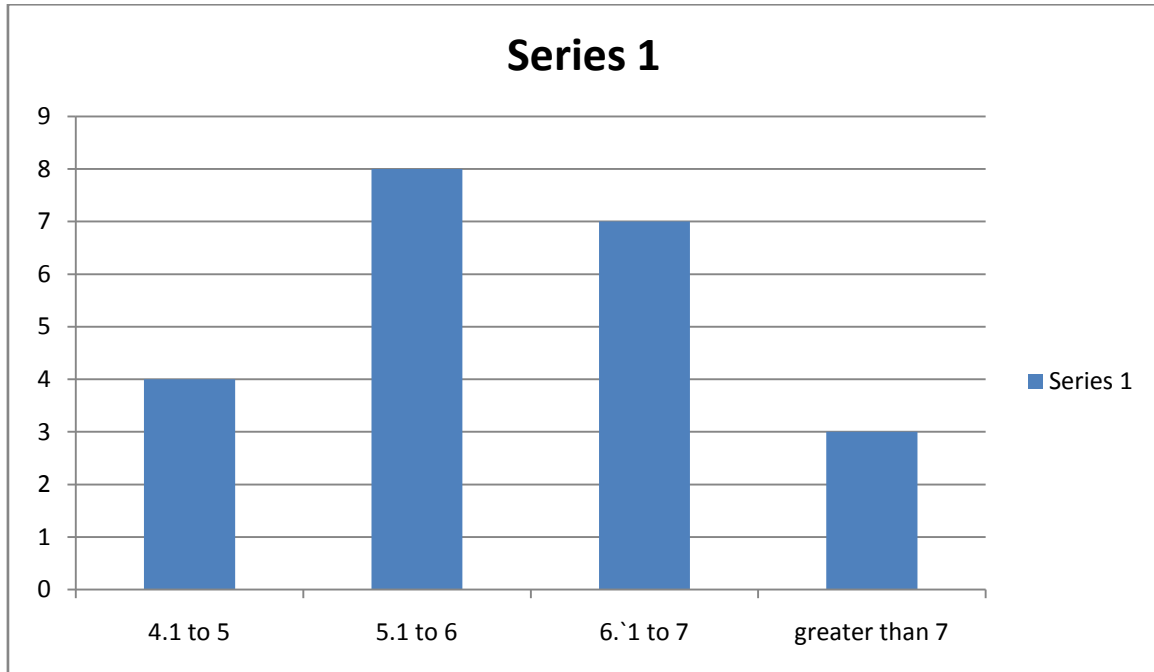
	4.1 TO 5	5.1 TO 6	6.1 TO 7	GREATER THAN 7
TOTAL	4	8	7	3
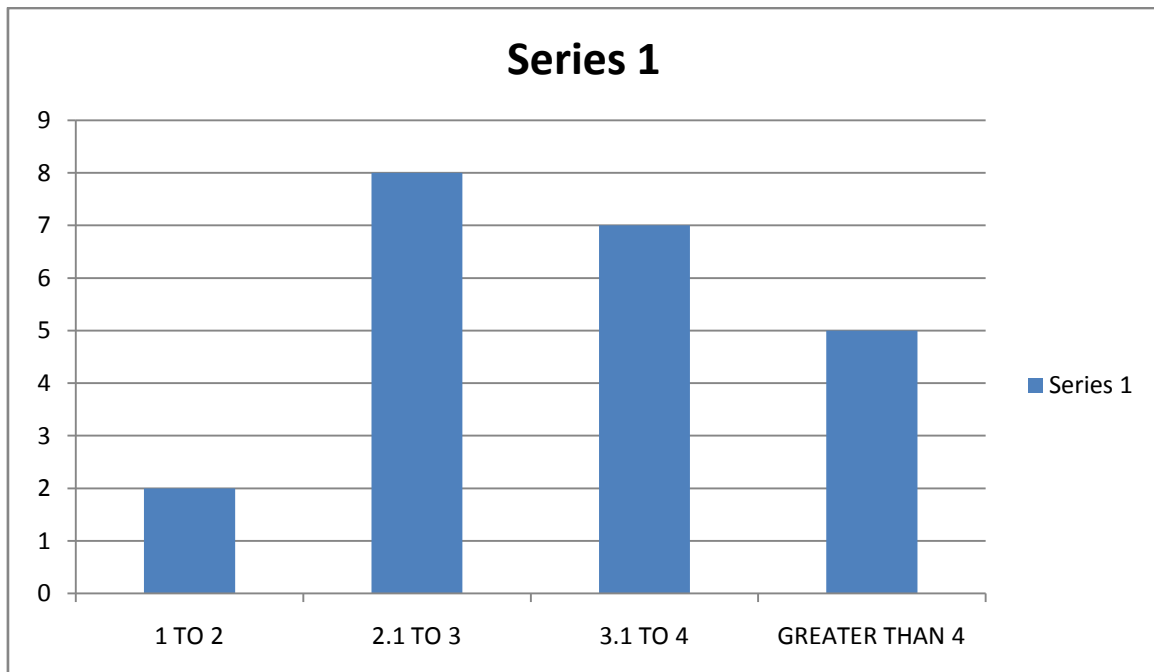
	1 TO 2	2.1 TO 3	3.1 TO 4	GREATER THAN 4
TOTAL	2	8	7	5

The comparison of serum total proteins and rates of spontaneous closure showed no significance statistically with a p value of 0.26 whereas comparison of serum albumin levels and the rates of spontaneous closure showed a p value of 0.08.
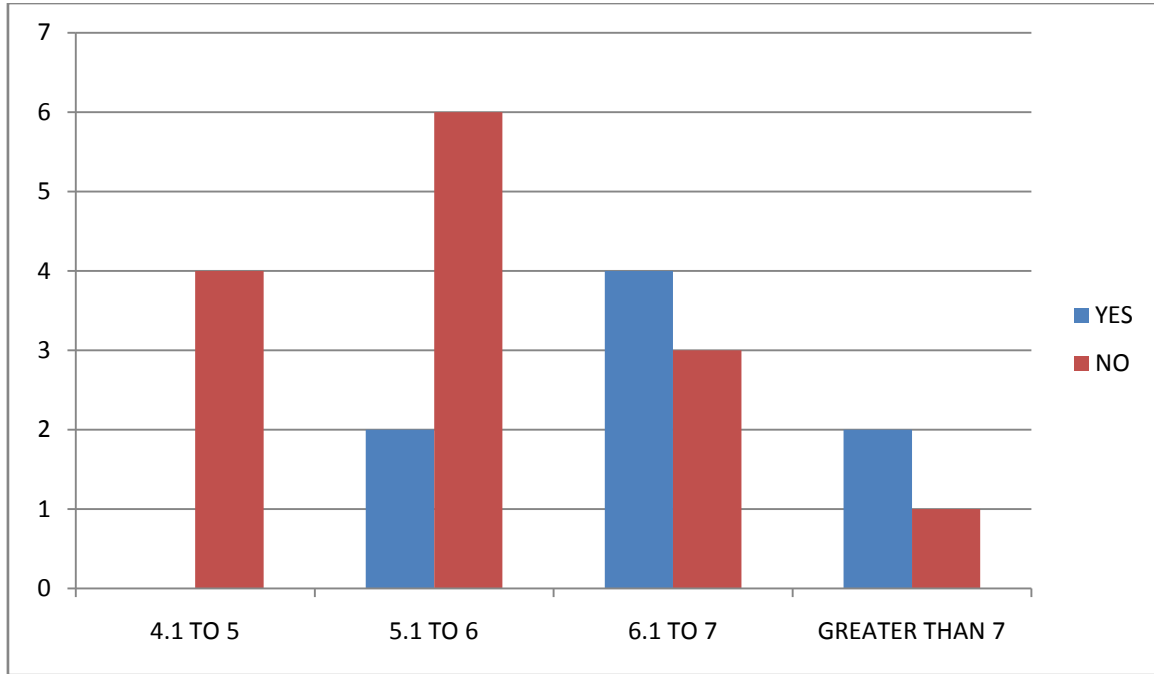
	4.1 TO 5	5.1 TO 6	6.1 TO 7	GREATER YHAN 7
YES	0	2	4	2
NO	4	6	3	1
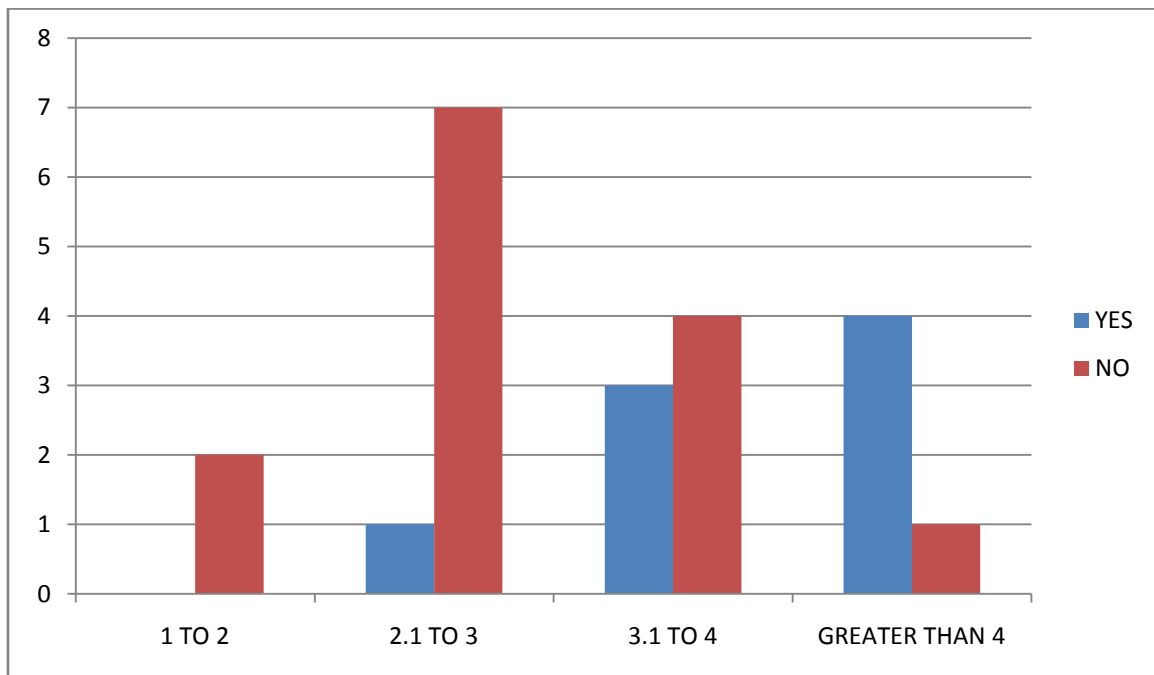
	1 TO 2	2.1 TO 3	3.1 TO 4	GREATER THAN 4
YES	0	1	3	4
NO	2	7	4	1

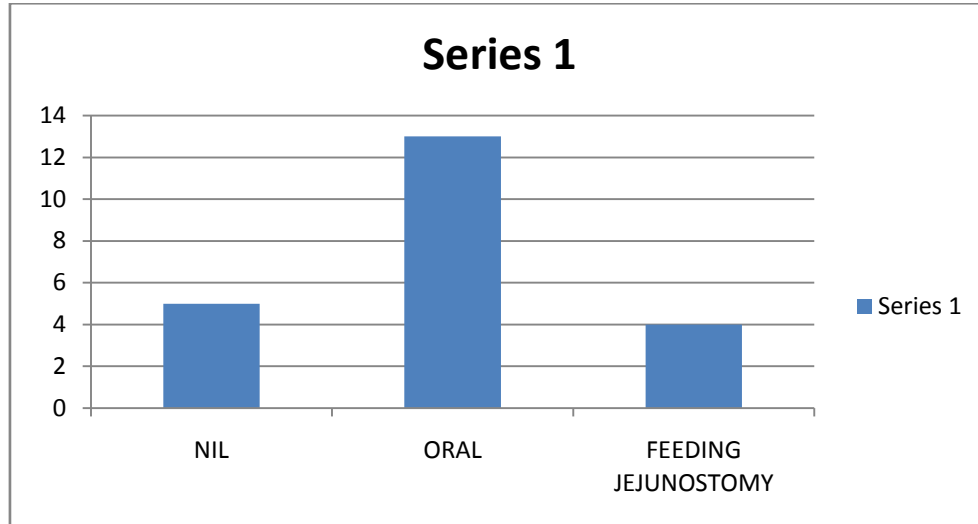Of the 22 patients, 8 patients had surgical closure of the fistula. The mean time interval between the fistula onset and the time of surgery is 35 days. During this time 15 patients received Total parenteral nutrition and 17 patients received enteral nutrition either by oral or through a feeding jejunostomy.

| Reduction of fistula output	Yes	No
Yes	15	6
No	0	1
Grand total	15	7
Total parenteral nutrition received		

There was no statistical significance of total parenteral nutrition usage and decrease in fistula output. (p value = 0.21).

Comparing enteral nutrition and spontaneous closure yielded no significant results statistically. (p value = 0.22)

Enteral nutrition	Spontaneous closure	
	yes	No
Nil		5
Oral	7	6
Feeding jejunostomy	1	3
Grand total	8	14

All patients received Injection Octreotide 100 μg subcutaneously every 8th hourly. It was continued for 14 days if the fistula output is reducing but it was stopped after 5 days if there is no reduction in the fistula output

Comparing the site of the fistula to the reduction of the fistula output we could see that those that responded to octreotide are usually gastric and small intestinal fistulas whereas the caecal and colonic fistulas showed no immediate reduction of output even using for 5 days. Though this result is not statistically significant. (P value of 0.6)
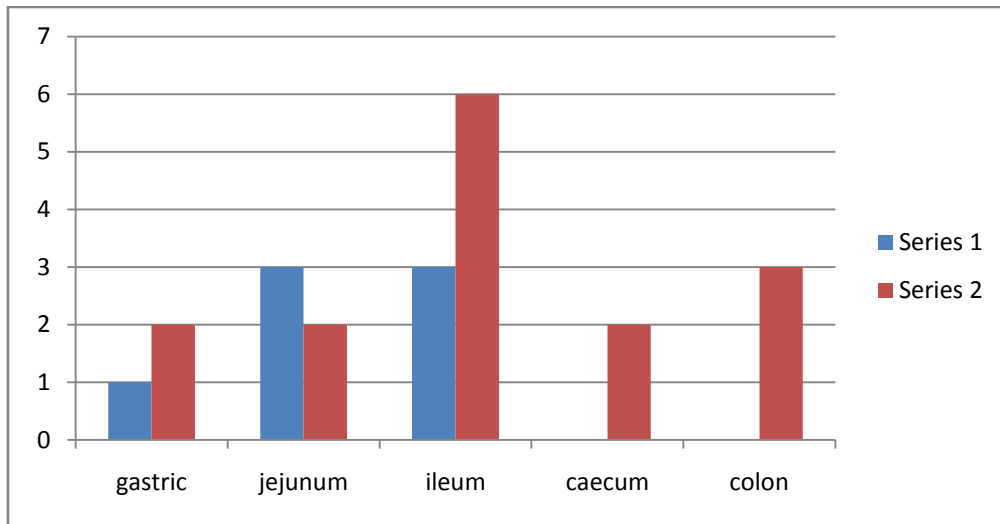
|	GASTRIC	JEJUNUM	ILEUM	CAECUM	COLON
YES	1	3	3		
NO	2	2	6	2	3

P VALUE -0.6

In this study 5 patients had hyponatremia with a serum Sodium level of less than 130 meq/l and 14 patients had hypokalemia. Of those patients 3 had sever hypokalemia with serum potassium levels less than 2.5 meq/l while 6 patients had moderate hypokalemia (serum potassium 2.5 to 3 meq/l) and 4 patients had mild hypokalemia (serum potassium levels 3 to 3.5meq/l). One patient had hyperkalaemia which was probably due to coexistent severe acute renal failure. Comparing the prevalence of hypokalemia and fistula output we could see that no patients with low output fistulas had moderate or severe hypokalemia (p value = 0.26) while patients while only 3 of the 10 patients with high output fistulas had no hypokalemia (p value = 0.31).
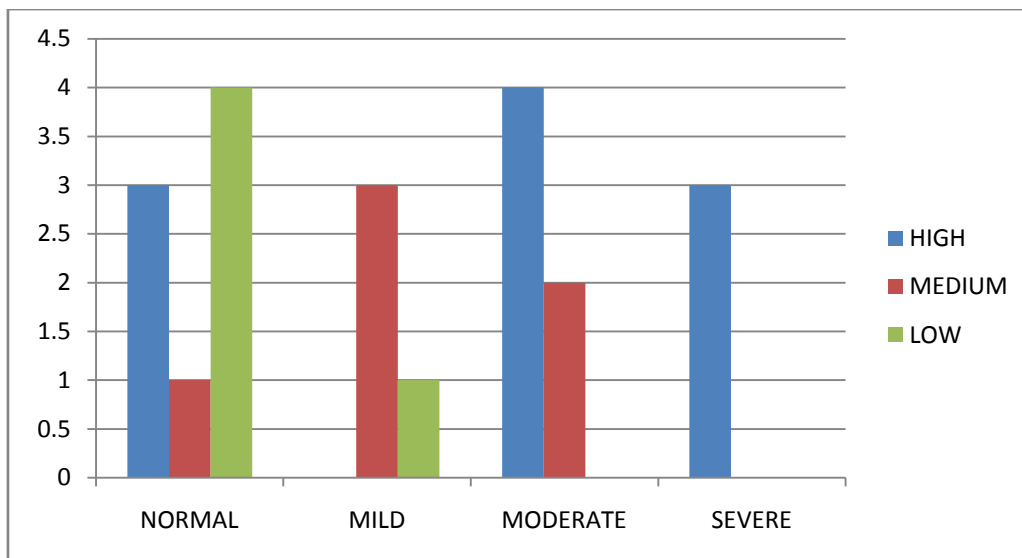
	NORMAL	MILD	MODERATE	SEVERE
HIGH	3	0	4	3
MEDIUM	1	3	2	0
LOW	4	1	0	0

Of the total, 9 patients in this study had large defects in the abdominal wall surrounding the fistula. These large defects where significantly associated with high output fistulas (p value = 0.02)
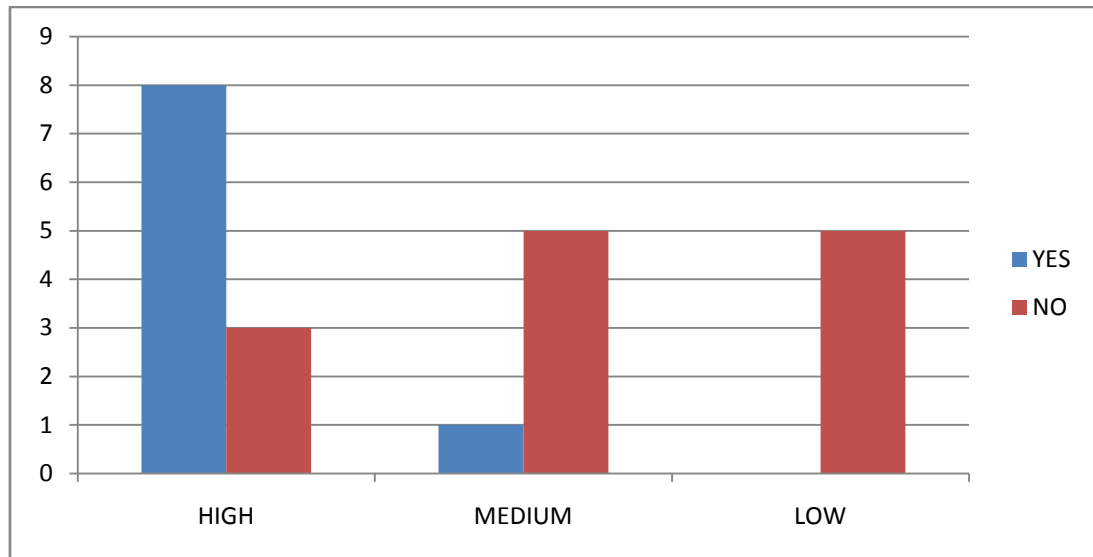
|	HIGH	MEDIUM	LOW
YES	8	1	0
NO	3	5	5

P VALUE -0.26

The main complications noted in this study were anemia, sepsis, electrolyte imbalances, renal failure, weight loss, skin excoriation and liver failure.

Fistula Output	renal Failure	Liver Failure	Sepsis	Hyponatre-mia	Hypokalem-ia	Anemia	Weight Loss	Mortality
High	11	7	11	4	8	5	7	4
Medium	3	2	6	1	6	2	4	2
Low	2	0	3	0	1	1	3	0
Total	16	9	20	5	15	8	14	6

The table below lists the complications according to the output of the fistulas.

18 of the 22 patients had skin excoriations due to fistula effluent irritating the skin around the fistula. The average hospital stay of the patients is 32.45 days with a standard deviation of 17.88. 6 of the 22 (27.27%) patients died in the study and of which 4 (18.18%) had high output fistulas and 2 (9.09%) had medium output fistulas. They were no mortality recorded in patients with low output fistulas (p value=0.5).

4 of the 6 mortalities occurred within the first 10 days of developing a fistula. One patient died in the 16th day and one other patient died in the 42nd day
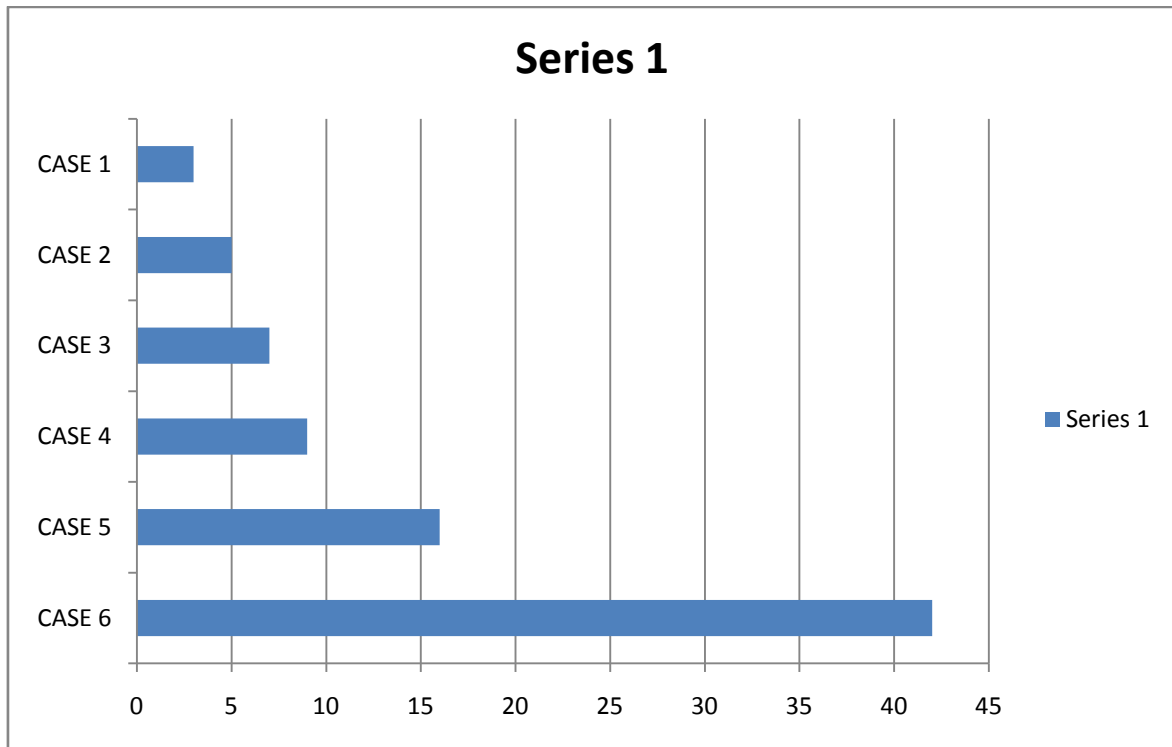
2 out of 5 patients with jejunal fistulas and 4 out of 9 patients with ileal fistulas died in this study.
The relationship between renal failure and mortality is not statistically significant with a p value of 0.22. Where as the presence of liver failure is statistically significant indicator of mortality with a p value of 0.03. All patients who died had presence of liver failure before their death.
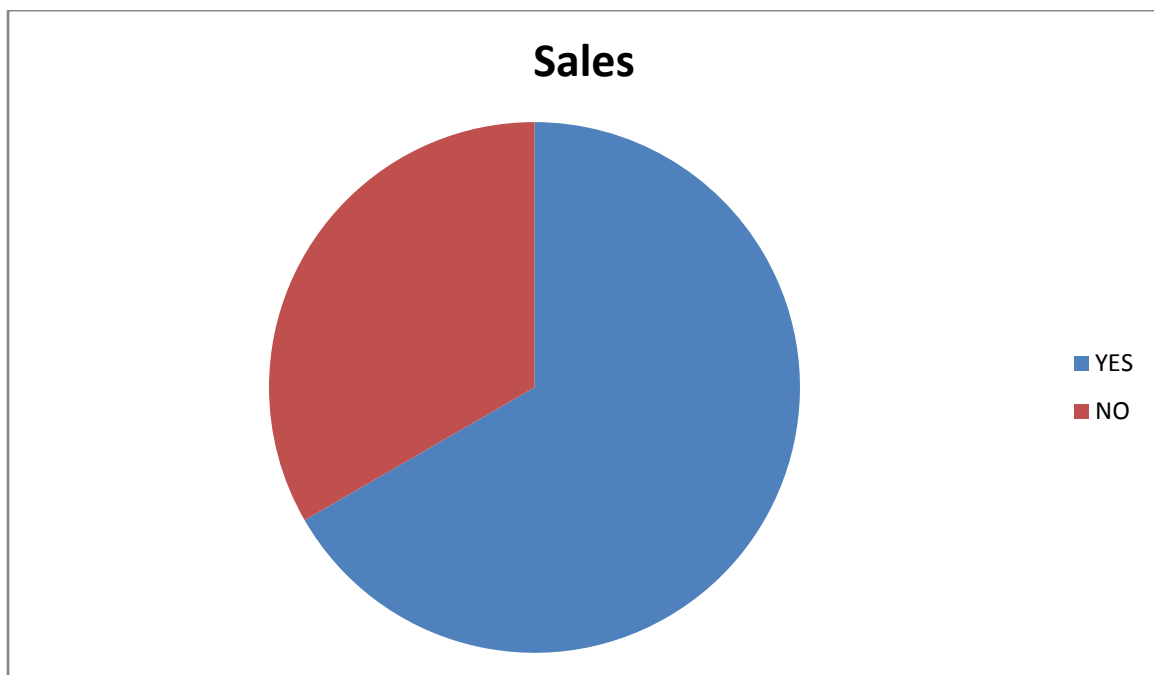
IV. Discussion
Enterocutaneous fistula provides a great challenge to the surgeon. It needs a holistic approach in management with combined medical, surgical and intensive care unit teams. In this study of 22 patients who developed post-surgical fistula the mean age of the patients was 55 with a standard deviation of 10 years Majority of the patients were within 50 to 70 years of age. The most common cause of the fistula was due to

anastomotic leak, followed by hollow viscous perforation, post appendicectomy and then inadvertent enterotomy. In a large case series done by Rose et al (8) with 114 cases the most common cause was due to "surgical misadventure" accounting for about 76% of the postoperative fistulas. In this study anastomotic leak accounts for 69% of the cases while there was only one case of inadvertent enterotomy Majority of the cases in this study (91%) are done in an emergency setting either due to acute intestinal obstruction or hollow viscous perforation are in acute gangrenous appendicitis. Only in 2 of the 22 patients elective surgery was done. One patient developed a leak after a right hemicolectomy done for ascending colon malignancy for which ileo-transverse anastomosis was done and she developed a leak which resolved spontaneously. The other patient had a transverse loop colostomy done for sigmoid colon anastomosis for sigmoid.

The patients with emergency surgery done usually has increased risk for formation of fistulas because they usually present with sepsis, with compromised hemodynamics, renal and/or liver functions. In this setting they are also the patients who are usually poorly nourished hailing from a low socioeconomic class. This is similar to a study by Kumar S et al (42) which showed 11% of the surgeries done in an emergency setting developed fistula whereas, no one developed fistula following an elective surgery Ileum was the most common site for formation of enterocutaneous fistula accounting for 41% of the cases, followed by jejunum, stomach, colon and caecum. Ileal fistulas were almost due to anastomotic leak. Gastric fistulas were all due to large gastric perforations for which omental patch closure was done. The patients then developed fistula. One of the gastric fistulas closed spontaneously whereas the other two required surgical correction. Jejunal fistulas never had spontaneous closure. Feeding was given through a feeding jejunostomy tube distal to the fistula. The biliary and pancreatic juices from the fistula were refed into the feeding jejunostomy. This prevented the patients from developing or worsening of electrolyte abnormalities Though spontaneous closure was not significantly associated with the site of the fistula it was significantly associated with the output of the fistula. There is no rationale in waiting for a high output fistula to spontaneously close whereas a low output fistula can be managed expectantly for spontaneous closure to occur.

Medium output fistulas on the other hand have varying results. Other factors like length of the tract, presence of distal obstruction and nutritional status of the patient comes into play. Though no statistical significance was achieved in this study for presence of distal obstruction and spontaneous closure of the fistula it is documented in a lot of studies as already reviewed earlier. This may be because only 2 patients had distal obstruction in our study and in both of these patients no spontaneous closure occurred

The mean duration of spontaneous closure in this study was 21.7 days with a standard deviation of 10.4 days. The longest to spontaneously close was 40 days which was a colonic fistula, the shortest was within 9 days for a caecal fistula which developed post appendicectomy for a gangrenous appendix.
 The presence of coexisting diabetes mellitus or systemic hypertension had no contributions in the spontaneous closure of a fistula a seen in this study.

Almost all patients in this study were under nourished, only 3 patients had a serum total protein of 7 g/dl or higher, while 12 patients had protein level of 6 g/dl or lower. Comparing these with the rates of spontaneous closure yielded no statistical significance. 2 patients in this study had severe hypoalbuminemia and 15 patients had mild to moderate hypoalbuminemia. This may be explained by the catabolic state of the patient due to ongoing loss peptide rich fluids to the outside through the fistula. All patients with hypoalbuminemia have very low blood oncotic pressure which may lead to extravasation of fluid and its collection in third spaces this may lead to worsening of hemodynamics of the patient and may also lead to underestimate the fluid correction needed. Hypoalbuminemia was associated with spontaneous closure with a p value of 0.08. this shows that estimation of serum albumin levels rather than total proteins may lead to a little more accurate estimation of the patient's nutritional status 4 out of the 6 mortalities were within the first 10 days of fistula formation. This is the critical period in which the patient is in sepsis and has several metabolic and electrolyte abnormalities. Hypokalemia was the most common electrolyte abnormality observed in this study. This is more profound in proximal high output fistulas. Only one patient with a low output fistula developed hypokalemia. Other electrolyte abnormalities include hyponatremia and hypocalcaemia.

The patients were invariably in sepsis, though, majority of them were in sepsis even pre-operatively. The common microorganisms isolated from the culture of the fistula output were coliforms like E. coli and Klebsiella species. Though no enterococci were isolated in this study this may further complicate because of resistances to majority of the higher antibiotics.

Nutrition is another key aspect in the management of enterocutaneous fistulas. From the advent of total parenteral nutrition there is a marked decrease in the mortality of the patient. In this study however, we were limited by the availability of total parenteral nutrition The patients received TPN 84 as long as it was available. We found no significant association between using TPN and spontaneous closure of the fistula.

Enteral nutrition must always be preferred over parenteral nutrition as it improves the gut flora and reduces the electrolyte abnormalities (43). Enteral nutrition may be provided through a feeding enterostomy tube distal to the fistula. Many times, it is not possible to do so. The concept of keeping a patient nil per oral and giving the 'bowel rest' is becoming obsolete. (43). Enteral nutrition protects the gut mucosa. Also, there is refeeding of the fistulous output into a mucous fistula or an enterostomy tube. Though this may be unacceptable by many patients, this enable a good method to continue enteral nutrition.

Octreotide, a somatostatin analogue is used to reduce the fistulous output by decreasing biliary, pancreatic and intestinal secretions. In this study it was found to be useful in fistulas arising from the stomach and small intestine only. No reduction of the output was observed for fistulas arising from the large bowel or caecum. Though there is no statistical significance in this study it may be used in regular management of these patients.

Other complications that arise commonly include anemia, weight loss, skin excoriations, intra-abdominal abscesses, and presence of a large defect in the abdominal wall. The presence of inflammation of the skin and subcutaneoustissue causes a problem while closing the abdomen after surgery. Skin excoriations must be vigorously treated with soothing creams and lotions and avoiding the pouring of the effluent onto the skin using isolated stoma bags or VAC dressings should be done.The mortality associated with this study is 27.2%. 66% of the deaths. occurred within the first ten days of developing the fistula. This is a critical period in which the patient is prone to develop sepsis and electrolyte abnormalities. The mortality is more with high output fistulas. Low output fistulas tend not to produce severe electrolyte imbalances and sepsis. 16 patients developed renal failure during the course of the disease. This is probably due dehydration, impaired renal perfusion and sepsis. The development of renal failure is not significantly associated with mortality. However, 9 patients developed Liver failure noted by elevation of SGOT and SGPT enzymes. This occurred as a consequence of severe disseminated septicaemia with multi-organ dysfunction. No patient who received TPN had elevated liver parameters in this study. Liver failure due to MODS is a good predictor of mortality with a p value of 0.03Blood Transfusions were given to 14 of the 22 patients the need for blood transfusions was not only decided by the haemoglobin and the hematocrit but also the hemodynamic status of the patients

The mean hospital stay of the patient is 32 days. This causes significant distress to the patients and their families. The longest stay was for 65 days. The patient also has the stigma of feculent smell and discharge. This also causes significant psychological stress to the patient. Adequate and proper counselling must be given to the patients and their relative to overcome this.

Though mortality of enterocutaneous fistula is high, aggressive management of the patient in the initial 2 weeks of the treatment and prevention of excessive excoriation of the abdominal wall and control of sepsis, and providing adequate nutrition can give good results and can cure the patient

V. Conclusion

Enteric fistulas, occurring spontaneously or in the postsurgical period, represent a significant management challenge and may result in both morbidity and occasionally mortality for the patient. The care in these patients may be complex and has led to the establishment of specialized intestinal failure units, aimed at optimizing outcome. This study is restricted only to postoperative fistulas. Spontaneous fistulas occurring due to an underlying bowel pathology is not discussed and studied. Also, there are not several randomised control studies for proper nutrition and use of pharmacological agents and varying techniques for surgery. Use of vacuum assisted dressings or stoma wound management appliances for management of fistula was not feasible in this study. Their optimum usage may further improve the outcome of the disease.

Also, the key to surgical resection od the fistula and restoring bowel continuity is the timing of the surgery. Early surgical intervention in a hemodynamically unstable patient leads to increased mortality. Properly staged definitive procedure after correcting the sepsis and improving the nutrition of the patient leads to the best results.

Although parenteral nutrition and bowel rest may be often advocated, enteral nutrition must be initiated as soon as possible with supplement of parenteral nutrition. There is no adequate number of randomised trials for purely parenteral vs enteral nutrition. There is no evidence to suggest that parenteral nutrition alone and giving 'bowel rest' is beneficial for the patient.

General principles of care must include

(1) early recognition and stabilization of patients with fistulas combined with control of sepsis and provision of nutritional support;

(2) investigation of the anatomic and etiological characteristics of each fistula, thus providing information about the likelihood of spontaneous closure or need for operative management;

(3) decision making regarding the approach to management, including the involvement of a multidisciplinary team, will provide the best possibility of resolution of the fistula;
 (4) definitive surgical therapy in a controlled setting; and
(5) postoperative care including physical rehabilitation and emotional support, which together help the patient return to their premorbid condition.

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